REMARKS

In reply to the Office Action of January 22, 2004, claim 34 has been amended to clarify the claimed invention. Applicant has further added claims 46-77. Applicant submits that these claims are readable on the elected species and do not contain new matter. Applicant hereby requests reconsideration of the application, in view of these amendments and the remarks which follow.

I. Brief Description of Currently Amended Claims 34-45 and Newly Added Claims 46-53

Claims 34-53 are directed to a biological suspension processing system comprising, inter alia: a blood treatment device for treating one or more components of a biological suspension; a human subject; a first fluid flow path, wherein said first fluid flow path is in continuing, direct communication with the vascular system of the human subject and the treatment device for introducing blood from the human subject into the treatment device; a second fluid flow path communicating with the treatment device for withdrawing a constituent of the blood from the treatment device; a third fluid flow path communicating with the treatment device for withdrawing another constituent of the blood from the treatment

device; and at least one microelectromechanical sensor communicating with one of said fluid flow paths for sensing either a biological or a chemical characteristic of the fluid within the flow path.

IA. Mian Neither Discloses Nor Suggests the Arrangement of Claims 34-53

Claims 34-36 and 38-45 stand rejected under 35 U.S.C. §102(e) as being anticipated by Mian et al. (U.S. 2001/0055812 A1), hereinafter "Mian." The office action states that Mian discloses the biological suspension processing system as claimed by the Applicant. More specifically, it states that "Mian discloses a centrifugal blood processing system having a location (C1) where the patient places his lanced finger; at this time, the fluid flow path of C1 is in communication with the vascular system of the patient." According to the Office Action, "a plurality of flow paths C2-C5 are provided for receiving the separated components (280) to (285), wherein the components can be withdrawn from the device (286). The device is a microanalytic system that includes electromechanical means (0099) and microchannels that include microsensors as disclosed by the applicant (0177) to (0208) and (0218)."

Applicant's claimed invention is readily distinguished from Mian and the attempted combination of various aspects of Mian as set forth by the office action. More specifically, Mian's Blood Composition Determination device has a first, second, and third mircochannels routed in a circular arrangement about a disk. (¶284) "In conjunction with the microchannel diameter information and the pattern of orientation of the channels on the disk, pressure data can be used to determine flow rates at a particular rotational speed. This information can then be used by the microprocessor to adjust disk rotational speed to control fluid movement on the disk." (¶284).

In contrast, Applicant's claimed invention comprises a fluid path for actually communicating blood ("in continuing, direct, communication") from a patient to a treatment device, such as centrifuge. Typically, this requires significant volumetric flow rates that can be up to about 50-70 ml/min or more. Microchannels are grossly insufficient and impractical for such an application. In further contrast, the first MEM sensor communicates with the fluid flow paths to sense biological and chemical characteristics of the fluid within the flow path such as red cell count, platelet count, lipid level, blood type or markers representative of pathogen presence; white cell count, red cell hematocrit and platelet density; or white

cell count, packed red cell hematocrit, platelet dose, pH, or gas partial pressure.

Mian is directed to an entirely different system, where very small isolated sample are processed discontinuously through microchannels. There is no actual treatment device, no fluid flow paths directly communicating between a human and the treatment device, and no MEM sensors communicating with such fluid flow paths in the Mian patent.

It is further submitted that Mian does not disclose or suggest the features of the newly added dependent claims, such as a fluid management module adapted to receive blood from the vascular system of the human subject and control the amount of blood introduced into the treatment device (claim 46); or a container communicating with the second fluid flow path for receiving the withdrawn constituent, or data storage media carried by the container (claims 47-53).

In view of the foregoing amendment and remarks, Applicant respectfully requests withdrawal of the 35 U.S.C. §102(e) rejection and allowance of these claims.

IB. The Prince-Bullister Combination Does not Render Applicant's Arrangement of Claims 34-53 Obvious

Claims 34-35 and 37 also stand rejected under 35 U.S.C. §103(a) as being unpatentable over Prince (U.S. Patent 5,178,603) in view of Bullister et al. (U.S. 6,171,253 B1). The office action states that "Prince teaches an apheresis system for the treating/returning blood to a patient via the system shown in figure 1 including a plasma separator (treatment device) and blood pump controlling blood flow to the device and including numerous pressure sensors." Although the office action correctly states that Prince does not disclose a MEM sensor, it concludes that when combined with the MEM blood pressure sensor of Bullister, Applicant's claimed invention is rendered obvious.

Applicant submits that Prince teaches a system for controlling blood flow through blood pressure sensors, but does not teach using MEM blood pressure sensors. In an effort to overcome this deficiency, the office action combines Prince with Bullister, which teaches MEM blood pressure sensors. Nevertheless, this Prince-Bullister combination does not render Applicant's claimed invention obvious. In contrast to both Prince and Bullister, Applicant's claimed invention as amended herein is directed to a system employing a microelectrome-chanical sensor "for sensing either a biological or chemical characteristic of the fluid within the flow path." In other

words, the sensor senses a biological or chemical characteristic of the fluid itself rather than the transport characteristics of the fluid stream such as flow rate or pressure as mentioned in Prince.

For example, in the specification, Applicant has described the use of MEM sensors in sensing and detecting red cell count, platelet count, lipid level, blood type, markers representative of pathogen (viral or bacterial presence), white cell count, red cell hematocrit, platelet density, platelet dose, pH, or gas partial pressure. *See* pg. 22, lns 9-11; pg. 23, lns. 9-11; pg. 24, lns. 9-10 of the specification. It is important to note that the foregoing list is not comprehensive, but is merely exemplary of the characteristics that may be sensed. Other such characteristics may be sensed so long as it is a biological or chemical characteristic of the fluid itself. Therefore, Applicant's claimed invention may be readily distinguished from the Prince-Bullister combination.

It is further submitted that the Prince-Bullister combination does not render obvious the features of the newly added dependent claims, such as a fluid management module adapted to receive blood from the vascular system of the human subject and control the amount of blood introduced into the treatment device (claim 46); or a container communicating with

the second fluid flow path for receiving the withdrawn constituent or data storage media carried by the container (claims 47-53).

Accordingly, in view of the foregoing remarks, Applicant respectfully requests withdrawal of the 35 U.S.C. §103(a) obviousness rejection and allowance of these claims.

II. Brief Description of Newly Added Claims 54-72

Claims 54-72 are directed to a biological suspension processing system comprising a blood treatment device for treating one or more components of a biological suspension; a human subject; a first fluid flow path, wherein said first fluid flow path is in continuing, direct communication with the vascular system of the human subject and the treatment device for introducing blood from the human subject into the treatment device; a first microelectromechanical sensor communicating with said first fluid flow path for sensing an initial condition of the fluid within said first fluid flow path, said first sensor further generating a signal responsive to the initial condition of the fluid in said first fluid flow path; a second fluid flow path communicating with the treatment device for withdrawing a constituent of the blood from the treatment device; a second microelectromechanical sensor communicating with said second fluid flow path for sensing either an in-process condition or a

final product condition of the fluid within said second fluid flow path, said second sensor further generating a signal responsive to the in-process condition or final condition of the fluid in said second fluid flow path; and a controller adapted to receive the first and second sensor signals and to control the treatment device in response thereto.

IIA. Mian Neither Discloses Nor Suggests the Arrangement of Claims 54-72

As stated above, the office action suggests that "Mian discloses a centrifugal blood processing system having a location (C1) where the patient places his lanced finger; at this time, the fluid flow path of C1 is in communication with the vascular system of the patient." According to the Office Action, "a plurality of flow paths C2-C5 are provided for receiving the separated components (280) to (285), wherein the components can be withdrawn from the device (286). The device is a microanalytic system that includes electromechanical means (0099) and microchannels that include microsensors as disclosed by the applicant (0177) to (0208) and (0218)."

Applicant's invention as claimed in Claims 54-72 is readily distinguished from Mian and the attempted combination of various aspects of Mian as set forth by the office action. More

specifically, Mian's Blood Composition Determination device has a first, second, and third mircochannels routed in a circular arrangement about a disk. (¶284) "In conjunction with the microchannel diameter information and the pattern of orientation of the channels on the disk, pressure data can be used to determine flow rates at a particular rotational speed. This information can then be used by the microprocessor to adjust disk rotational speed to control fluid movement on the disk." (¶284).

In contrast, Applicant's claimed invention comprises fluid paths for actually communicating (i.e., "continuing, direct communication") blood from a patient to a treatment device, such as centrifuge. As noted above, this typically requires significant volumetric flow rates that can be up to about 50-70 ml/min or more. Microchannels are grossly insufficient and impractical for such an application. In further contrast, the first MEM sensor communicates with the first fluid flow path to sense an initial condition, such as red cell count, platelet count, lipid level, blood type or markers representative of pathogen presence. Data from the initial condition sensor, typically in the form of an electrical signal, is fed to the control system for purposes of controlling the treatment device. Mian does not disclose either a first MEM sensor for sensing

initial conditions or a controller which controls the treatment device in response the initial data sensed by the first MEM sensor.

Moreover, in contrast to Mian, Applicant's claimed invention comprises a second MEM sensor which may sense an in-process characteristic such as white cell count, red cell hematocrit and platelet density. Data from the in-process condition MEM sensor is fed back to the control system for controlling the treatment device. Mian does not disclose such a second MEM sensor which senses an in-process condition, and Mian does not disclose a controller which controls the treatment device in response the in-process data sensed by the second MEM sensor.

Also, in contrast to Mian, the second MEM sensor may sense a final product condition, such as white cell count, packed red cell hematocrit, platelet dose, pH, or gas partial pressure. Data from this sensor may be relayed back to the controller for controlling the treatment device. Mian does not disclose a second MEM sensor which senses a final product condition, and Mian does not disclose a controller which controls the treatment device in response the final product data sensed by the second MEM sensor.

Mian is directed to an entirely different system, where very small isolated sample are processed discontinuously through microchannels. No actual treatment device, no fluid flow paths directly communicating between a human and the treatment device, no MEM sensors communicating with such fluid flow paths, and no controller responsive to signals from the MEM sensors to control the treatment device are shown or suggested in Mian.

It is further submitted that Mian does not disclose or suggest features of the newly added dependent claims.

In view of the foregoing amendment and remarks, Applicant respectfully requests allowance of these claims.

IIB. Prince Nor Bullister Neither Discloses Nor Suggests the Arrangement of Claims 54-72

As stated above, the office action suggests that "Prince teaches an apheresis system for the treating/returning blood to a patient via the system shown in figure 1 including a plasma separator (treatment device) and blood pump controlling blood flow to the device and including numerous pressure sensors." The office action correctly states that Prince does not disclose a MEM sensor. The office action combines Prince with Bullister, on the ground that Bullister teaches a MEM blood pressure sensor. Nevertheless, it is respectfully submitted that this

Prince-Bullister combination does not render Applicant's claimed invention obvious.

Although Prince does show a system for controlling blood flow through a blood pressure sensor, it does not teach or suggest using MEM sensors that sense an initial fluid condition and that sense either an in-process or a final product condition and that send signals to a controller to thereby control the treatment device.

In contrast to both Prince and Bullister, Applicant's claimed invention is directed to a suspension processing system including, inter alia, a first MEM sensor for sensing an initial condition and a second MEM sensor for sensing an in-process or final condition. Data from the initial condition sampling, in the form of an electrical signal, may be fed back to the control system for purposes of controlling the treatment device.

With respect to the in-process or final product condition MEMS sensor, which is neither taught nor disclosed by Bullister and Prince, a signal from that sensor is also fed back to the control system **52** for controlling the treatment device.

The Prince-Bullister combination does not disclose or otherwise suggest this combination of treatment device, controller, initial condition MEM sensor, and either an in-process or final product condition MEM sensor, with signal

generation to a controller from the both sensors for controlling the treatment device.

Accordingly, in view of the foregoing remarks, Applicant respectfully requests allowance of these claims.

III. Brief Description of Newly Added Claims 73-81

Claims 73-81 are directed to A biological suspension processing system comprising:a blood treatment device for treating one or more components of a biological suspension; a human subject; a first fluid flow path, wherein said first fluid flow path is in continuing, direct communication with the vascular system of the human subject and the treatment device for introducing blood from the human subject into the treatment device; a first microelectromechanical sensor communicating with said first fluid flow path for sensing an initial condition of the fluid within said first fluid flow path, said first sensor further generating a signal responsive to the initial condition of the fluid in said first fluid flow path; a second fluid flow path communicating with the treatment device for withdrawing a constituent of the blood from the treatment device; a second microelectromechanical sensor communicating with said second fluid flow path for sensing either an in-process condition or a final product condition of the fluid within said second fluid

flow path, said second sensor further generating a signal responsive to the in-process condition of the fluid in said second fluid flow path; a third fluid flow path communicating with the treatment device for withdrawing another constituent of the blood from the treatment device; a third microelectromechanical sensor communicating with said third fluid flow path for sensing a final product condition of the fluid within said third fluid flow path, said third sensor further generating a signal responsive to the final product condition of the fluid in said third fluid flow path; and a controller adapted to receive the first, second, and third sensor signals and to control the treatment device in response thereto.

IIIA. Mian Neither Discloses Nor Suggests the Arrangement of Claims 73-81

As stated above, the office action suggests that "Mian discloses a centrifugal blood processing system having a location (C1) where the patient places his lanced finger; at this time, the fluid flow path of C1 is in communication with the vascular system of the patient." According to the Office Action, "a plurality of flow paths C2-C5 are provided for receiving the separated components (280) to (285), wherein the

components can be withdrawn from the device (286). The device is a microanalytic system that includes electromechanical means (0099) and microchannels that include microsensors as disclosed by the applicant (0177) to (0208) and (0218)."

Applicant's invention as claimed in Claims 73-81 is readily distinguished from Mian and the attempted combination of various aspects of Mian as set forth by the office action. More specifically, Mian's Blood Composition Determination device has a first, second, and third mircochannels routed in a circular arrangement about a disk. (¶284) "In conjunction with the microchannel diameter information and the pattern of orientation of the channels on the disk, pressure data can be used to determine flow rates at a particular rotational speed. This information can then be used by the microprocessor to adjust disk rotational speed to control fluid movement on the disk." (¶284).

In contrast, Applicant's claimed invention comprises a fluid path for actually continuously communicating blood from a patient to a treatment device, such as centrifuge. Typically, this requires significant volumetric flow rates that can be up to about 50-70 ml/min or more. Microchannels are grossly insufficient and impractical for such an application. In further contrast, the first MEM sensor communicates with the

first fluid flow path to sense an initial condition, such as, but not limited to, red cell count, platelet count, lipid level, blood type or markers representative of pathogen presence. Data from the initial condition sensor, typically in the form of an electrical signal, is fed to the control system for purposes of controlling the treatment device. Mian does not disclose either a first MEM sensor for sensing initial conditions or a controller which controls the treatment device in response the initial data sensed by the first MEM sensor.

Moreover, in contrast to Mian, Applicant's claimed invention comprises a second MEM sensor which may sense an in-process characteristic such as, but not limited to, white cell count, red cell hematocrit and platelet density. Data from the in-process condition MEM sensor is fed back to the control system for controlling the treatment device. Mian does not disclose such a second MEM sensor which senses an in-process condition, and Mian does not disclose a controller which controls the treatment device in response the in-process data sensed by the second MEM sensor.

Also, in contrast to Mian, Applicant's claimed invention comprises a third MEM sensor which may sense a final product condition such as, but not limited to, white cell count, packed red cell hematocrit, platelet dose, pH, or gas partial pressure.

Data from this sensor may be relayed back to the controller for controlling the treatment device. Mian does not disclose such a third MEM sensor which senses a final product condition, and Mian does not disclose a controller which controls the treatment device in response the final product data sensed by the third MEM sensor.

Mian is directed to an entirely different system, where very small isolated sample are processed discontinuously through microchannels. No actual treatment device, no fluid flow paths directly communicating between a human and the treatment device, no MEM sensors communicating with such fluid flow paths, and no controller responsive to signals from the MEM sensors to control the treatment device are shown or suggested in Mian.

It is further submitted that Mian does not disclose or suggest features of the newly added independent claims and the newly added dependent claims relating thereto.

In view of the foregoing amendment and remarks, Applicant respectfully requests allowance of these claims.

IIIB. Prince Nor Bullister Neither Discloses Nor Suggests the Arrangement of Claims 73-81

As stated above, the office action suggests that "Prince teaches an apheresis system for the treating/returning blood to

a patient via the system shown in figure 1 including a plasma separator (treatment device) and blood pump controlling blood flow to the device and including numerous pressure sensors." The office action correctly states that Prince does not disclose a MEM sensor. The office action combines Prince with Bullister, on the ground that Bullister teaches a MEM blood pressure sensors. It is respectfully submitted that this Prince-Bullister combination does not render Applicant's claimed invention obvious.

Although Prince does show a system for controlling blood flow through a blood pressure sensor, it does not teach or suggest using MEM sensors that sense an initial fluid condition and that sense either an in-process or a final product condition and that send signals to a controller to thereby control the treatment device.

In contrast to both Prince and Bullister, Applicant's claimed invention is directed to a suspension processing system including, inter alia, a first MEM sensor for sensing an initial condition, a second MEM sensor for sensing an in-process condition, and a third MEM sensor for sensing a final product condition. Data from the initial condition sampling, in the form of an electrical signal, may be fed back to the control system for purposes of controlling the treatment device.

With respect to the in-process and final product condition MEMS sensor, which are neither taught nor disclosed by Bullister and Prince, a signal is also fed back to the control system for controlling the treatment device.

The Prince-Bullister combination does not disclose or otherwise suggest this combination of treatment device, controller, initial condition MEM sensor, and either an in-process or final product condition MEM sensor, with signal generation to a controller from the both sensors for controlling the treatment device.

Accordingly, in view of the foregoing remarks, Applicant respectfully requests allowance of these claims.

Conclusion

In view of all the foregoing, reconsideration and allowance of all pending claims are respectfully requested. If any additional fee should be required, the Commissioner is hereby authorized to charge Deposit Account No. 50-1039

Respectfully submitted,

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